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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,880

05/03/2007

Joon-Haeng Rhee

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EXAMINER

ARCHIE, NINA

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,880	<b>Applicant(s)</b> RHEE ET AL.	
	<b>Examiner</b> Nina A. Archie	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/2/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/16/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

1. This Office is responsive to Applicant's amendment and response filed 6-2-09. Claims 1-9 are pending. Claims 1-3 and 7 have been amended. Claims 1-3 and 7-8 are under examination. Claims 4-6 and 9 are withdrawn from consideration. Claims 8-9 are new.

***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Acknowledgment is made of applicant's claim for foreign priority based on Foreign application REPUBLIC OF KOREA 10-2004-0001974 filed 1/12/2004. It is noted, however, that applicant has not filed a certified copy of the Foreign application REPUBLIC OF KOREA 10-2004-0001974 filed 1/12/2004 as required by 35 U.S.C. 119(b). Moreover, Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority the priority date is based on the priority document filed REPUBLIC OF KOREA 10-2004-0001974 filed 1/12/2004. To satisfy the requirement of 37 CFR 1.55(a) (2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy. However should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this application. Therefore, the effective (priority) date of the in the instant application is 1/12/2005.

***Election/Restrictions***

3. Examiner made a typographical error stating Applicants elected Sequences 5 and 6 in the office action mailed on 2/2/2009. Therefore SEQ ID NO: 3 has been withdrawn from consideration and SEQ ID NO: 4 is under examination.

***Information Disclosure Statement***

4. The information disclosure statement filed on 9/16/2009 has been considered. An initialed copy is enclosed.

***Objections/Rejections Withdrawn***

5. In view of the Applicant's amendments and remarks the following objections/rejections are withdrawn.

a) Rejection to claims 1-2 and 7 under 35 U.S.C. 102(b) as being anticipated by Wu et al 1989 Proc. Natl. Acad. Science Vol. 86 pgs. 4726-4730 is withdrawn in light of applicant's amendment thereto.

b) Rejection to claim 7 under 35 U.S.C. 112, second paragraph, is withdrawn in light of applicant's amendment thereto.

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Adarem et al WO 2002/085933A1 Date October 31, 2002.

Claims 1-2 and 7-8 are drawn to mucosal vaccine adjuvants comprising isolated bacterial flagellins as an active component (claim 1), wherein flagellins are originated from *Vibrio vulnificus*, *Salmonella typhimurium*, or *Listeria monocytogenes* (claim 2), wherein vaccine adjuvant are adjuvants for an anti-toxin vaccine; a live attenuated or killed vaccine; an anti-viral vaccine; an anti-cancer vaccine; an anti-sperm contraceptive vaccine; or a recombinant protein or peptide vaccine (claim 7), wherein the anti-toxin vaccine is against tetanus toxoid; the live attenuated or killed vaccine is against cholera and or typhoid fever; the anti-viral vaccine is against influenza and/or SARS; and the anti-cancer vaccine is against uterine cervical cancer (claim 8).

Adarem et al teach a method of inducing an immune response in an individual having a pathological condition, comprising administering to said individual an immunogenic amount of a flagellin polypeptide, wherein a flagellin polypeptide is isolated from *Salmonella typhimurium*

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(see claim 20 and 21) and further teach a flagellin purified from *Salmonella typhimurium* (see Example IV). Adarem et al teach an adjuvant in a vaccine formulation wherein immunomodulatory flagellin peptides contribute to the effectiveness of a vaccine by, for example, enhancing the immunity at a target tissue, such as mucosal immunity and also enhancing the immunogenicity of weaker antigens such as highly purified or recombinant/attenuated antigens (see pg. 33). Adarem et al teach innate immune response increases the immune response to an antigen by stimulating the adaptive immune response thus a combination of an immunomodulatory flagellin peptide, polypeptide with one or more antigens provides an effective vaccine for inducing an immune response in an individual (see pg. 33 lines 10-30).

As to independent claim 1 and dependent claims 2 and 7-8, regarding the recitation, “vaccine” (claims 1-2 and 7-8) and also regarding recitations, “wherein vaccine adjuvant are adjuvants for an anti-toxin vaccine; a live attenuated or killed vaccine; an anti-viral vaccine; an anti-cancer vaccine; an anti-sperm contraceptive vaccine; or a recombinant protein or peptide vaccine” (claim 7), “wherein the anti-toxin vaccine is against tetanus toxoid; the live attenuated or killed vaccine is against cholera and or typhoid fever; the anti-viral vaccine is against influenza and/or SARS; and the anti-cancer vaccine is against uterine cervical cancer” (claim 8) given that Adaram teach said mucosal adjuvant, said mucosal adjuvant would necessarily have the immunological and biological properties as that of the instant invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 3 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to dependent claims 3 and 7-8, the claims are indefinite by reciting improper Markush language. Alternative expressions are permitted if they present no uncertainty or ambiguity with

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respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “selected from the group consisting of A, B *and* C.”

***Conclusion***

8. No claims are allowed.

Claim 3 is objected to for containing language drawn to non-elected inventions

SEQ ID NO: 4 is free of the art of record.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner

GAU 1645

REM 3B31

/Robert A. Zeman/  
for Nina Archie, Examiner of Art Unit 1645